Remarks

Renumbering of Claims

Applicants acknowledge with appreciation the renumbering of claims 32-34 following claim 36 to claims 37-39 to correct the numbering error in the originally filed application. Applicants note that claims 37-39 have been cancelled above as being directed to non-elected subject matter.

Addition of Claims 40-43

Claims 40-43 have been added because original claims 6-9 were erroneously cancelled in the prior response dated January 25, 2002 to the restriction and election of species requirements. Original claims 6-9 fell within elected Group I, but did not contained the elected species. New claims 40-43 track claims 6-9 and are represented because, upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claims as provided by 37 C.F.R. § 1.141.

Specification Objection

The disclosure has been objected to because it was noted that the structure (X) on page 29 was missing a nitrogen in the pyrimidine ring. The structure (X) has been amended above to include the nitrogen. No new matter has been added because the mistake was obvious and the chemical name of the compound represented by structure (X) is set forth directly above the structure. In view of the amendment, applicants respectfully request withdrawal of this objection.

35 U.S.C. § 112, First Paragraph

Claims 1 and 10-12 have been rejected under 35 U.S.C. § 112, first paragraph, as it is alleged that these claims are not enabled with regard to estrogen agonists/antagonists as a class. Applicants respectfully assert that the invention claimed in claims 1 and 10-12 are fully enabled with regard to estrogen agonists/antagonists, and no undue experimentation is required to use the claimed invention. Claims 1 and 10-12 relate to the use of an estrogen agonist/antagonist alone or a combination of an estrogen agonist/antagonist with a cyclic guanosine 3',5'-monophosphate elevator, such as a PDEv inhibitor, for the treatment of sexual arousal disorder. Specifically, the Examiner states in the Office Action that

"Applicants disclose formula IA and the compounds of cancelled claims 6-9 as estrogen agonists/antagonists. No other estrogen agonists/antagonists are disclosed." The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. The factors to be considered in determining if any experimentation is undue were set forth in *In re Wands*, 8 U.S.PQ.2d 1400 (Fed. Cir. 1988). The factors are:

A.) The breath of the claims;

B.) The nature of the invention;

C.) The state of the prior art;

D.) The level of ordinary skill;

E.) The level of predictability in the art;

F.) The amount of direction provided by the inventor;

G.) The existence of working examples; and

H.) The quantity of experimentation needed to make or use the invention based on the disclosure.

Applicants assert that when the invention of the present claims is considered in view of the *Wands* factors, the present invention does not require undue experimentation to practice and has, therefore, been enabled. First, those skilled in the art are very familiar with estrogen agonists/antagonists and many are known as is illustrated by the numerous and structurally varied examples given in the specification of the present application, including the compounds of formulas I, IA, V, VI, Va, III, IV, and the compounds listed in claim 6. That estrogen agonists/antagonists are well known to those skilled in the art is further evident in that several estrogen agonists/antagonists are marketed products. For example raloxifene, an estrogen agonist/antagonist is sold by Eli Lilly as Evista® for the treatment of osteoporosis. Also, tamoxifen, another estrogen antagonist is sold by AstraZeneca for treatment of metastatic breast cancer and adjuvant treatment of breast cancer. Other compounds are presently in clinical trials including Wyeth's TSE-424. That estrogen agonists/antagonists products exist and that compounds are presently in human clinical trials demonstrates the familiarity of those skilled in the art with estrogen agonists/antagonists. Those skilled in the art are also readily able to determine if a compound is an estrogen agonist/antagonist because such assays are well known. An example of such an assay is set forth in the specification as Example 1, page 63. Therefore, it would not be undue experimentation to determine if a compound is an estrogen agonist/ antagonist. Once an estrogen

agonist /antagonist has been identified, it can, in accordance with the present invention, be administered to a patient to treat sexual arousal disorder. Because those skilled in the art are familiar with estrogen agonists/antagonists and are familiar with assays to determine if a compound is an estrogen agonist/antagonist, applicants respectfully assert that the present invention does not require undue experimentation and that the full scope of claims 1 and 10-12 is enabled. In view of the remarks made above, applicants respectfully request reconsideration and withdrawal of this rejection.

35 U.S. C. § 112, First Paragraph

Claims 1-5 and 10-11 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled for PDE_v inhibitors as a class. Specifically, it is stated in the Office Action that "applicants disclose formulae VII-XIA as PDE_v phosphodiesterase inhibitors. No other are disclosed." The standard and factors in determining enablement are set forth above. Applicants respectfully assert that the presently claimed invention is enabled and does not require undue experimentation because PDE_v inhibitors are well known to those skilled in the art, and assays to determine if a compound is a PDE_v inhibitor are also well known to those skilled in the art. An example of such an assay is disclosed in Journal of Urology, Volume 159, pages 2164-2171 (1998), which is cited at page 34, line 17 of the present specification. At least one marketed product that is a PDE_v inhibitor exists. This product is Viagra® sold by Pfizer for male erectile dysfunction. At least two other PDE_v compounds are in late stage clinical development - vardenafil and IC351 for male erectile dysfunction. Thus, those skilled in the art are familiar with PDE_v inhibitors and using standard assays are able to identify whether a compound is a PDE_v inhibitor. Moreover, the present specification exemplifies a structurally diverse class of PDE_v inhibitors and other compounds are known to those skilled in the art. The examples presented in the specification are intended to be representative examples of the PDE_v inhibitors that are known to those skilled in the art and are not intended to be an exhaustive list of all known PDE_v inhibitors. Recitation of additional PDE_v inhibitors in the specification is not necessary because a patent need not teach and preferably omits that which is well known in the art. See, MPEP, eighth edition, section 2164.01, titled "Test of Enablement", page 2100-174, second column.

Since those skilled in the art are familiar with PDE_v inhibitors, and are also familiar with assays to identify PDEv inhibitors, applicants respectfully assert that the

present invention is enabled for PDE_v inhibitors, and respectfully request reconsideration and withdrawal of this rejection.

Applicants believe that, in view of the amendments and remarks made above, this application is in condition for allowance. Reconsideration and allowance of claims 1-5, 10-12 and 40-43 is respectfully requested.

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Attachment
Marked Up Copy of Amended Paragraph